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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/591,199

06/13/2007

Zhao Yi Wang

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EXAMINER

SHAFFER, SHULAMITH H

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/591,199	<b>Applicant(s)</b> WANG, ZHAO YI	
	<b>Examiner</b> SHULAMITH H. SHAFER	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) 17-28 and 39-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-16, 29-38 and 52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/3/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **Detailed Action**

#### ***Status of Application, Amendments, And/Or Claims:***

The amendment received 12 January 2009 has been entered. Claims 12-14, 29, and 52 have been amended and amendment made of record.

Claims 1-52 are pending in the instant application. Claims 17-28 and 39-51 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 1-16, 29-38, and 52 are under consideration.

#### ***Information Disclosure Statement:***

The Information Disclosure statements (IDS), submitted on 3 December 2008, has been considered. The signed copy is attached.

### **Withdrawn Objections/Rejections**

#### ***Objections:***

The objection to Claim 12 is withdrawn in light of applicant's amendment to the claims.

#### ***Rejections:***

The following rejections under 35 U.S.C. 112, second paragraph are withdrawn as having been overcome by applicant's amendment:

Claim 13

Claims 14 and 16

Claim 29 as directed to recitation of "ER- $\alpha$ 36" and "ER- $\alpha$ 36 activity".

The rejection of Claim 52 under 35 U.S.C. 112, 2nd paragraph is withdrawn in view of applicant's persuasive arguments.

**Maintained Rejections/New Grounds for Objection/Rejection**

***Objections:***

Claims 30 and 34 are objected to as being duplicative claims. Claims 32 and 35 are objected to as being duplicative claims. Applicant is required to cancel one of duplicate claims.

***35 U.S.C. § 112, Second Paragraph:***

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of Claim 29 as an incomplete method claim is maintained for reasons of record and for reasons set forth below.

Applicant traverses the rejection (response of 1 December 2008, page 9, 6<sup>th</sup> paragraph). The reason for the traversal is:

Applicant is using the term “analyzing” in the sense of performing an analytical method and should not be construed as merely a mental or cognitive activity. Applicant’s specification describes how exemplary analytical methods may be performed.

Applicant’s arguments have been fully considered but are not found to be persuasive for the following reasons:

The Claim, as recited, is incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: active steps for detecting the polypeptide of interest, such as a contacting step in which the reaction of the sample with the reagents necessary for the assay is recited, and a detection step in which the reaction steps are quantified. The claim recites characteristics of the polypeptide, but does not recite specific method steps for

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detecting said polypeptide, as required by the preamble. While exemplary methods are recited in the specification, applicant is reminded that it is improper to read limitations or embodiments of the specification into a claim (See MPEP 2111.01). It is noted that this rejection could be obviated by an amendment incorporating the limitations recited in Claim 36 ("wherein the analyzing comprises contacting the cell with an antibody that specifically binds to an amino acid sequence depicted at SEQ ID NO:1, or an immunogenic fragment thereof.") into claim 29.

### **Claim Interpretation**

As previously discussed, the claims are drawn to an antibody that specifically binds to **an** amino acid sequence of SEQ ID NO:1 (Claim 1) or an antibody that specifically binds to **an** amino acid depicted at amino acids 13-27 of SEQ ID NO:1. These phrases encompass antibodies that bind to any portion of SEQ ID NO:1 or bind to any portion of amino acids 13-27 of SEQ ID NO:1. The claims would be anticipated by antibodies binding to any fragment of SEQ ID NO:1 or any fragment of amino acids 13-27 of two or more amino acid residues, if it were applicants intent to encompass such breadth.

### **35 U.S.C. § 102:**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of Claims 1-16 and 52 under 35 U.S.C. 102(e) as being anticipated by Rosen et al. (USPGPUB 2007/0015271, the '271 document, filed 27 April 2003) is maintained for reasons of record and for reasons set forth below.

Applicant traverses the rejection (response of 1 December 2008, page 13, last paragraph bridging page 14, 1<sup>st</sup> paragraph). The reason for the traversal is:

The teaching of Rosen fails to expressly describe an antibody that specifically binds to amino acids 90-95 of SEQ ID NO:5141. If one skilled in the art were to attempt to generate antibodies against a polypeptide having the amino acid sequence of SEQ ID NO:5141, the skilled person would not necessarily produce an antibody that specifically binds to amino acids 90-95 of SEQ ID NO:5141. Consequently, Rosen fails to set forth teaching that inherently discloses an antibody that specifically binds to SEQ ID NO:1 of the instant invention or an immunogenic fragment thereof.

Applicant's arguments have been fully considered but are not found to be persuasive for the following reasons:

The '271 document teaches antibodies to the polypeptides taught in the referenced document, which include antibodies to the polypeptide of SEQ ID NO:5141, and methods for making said antibodies [for example, abstract, paragraph 002, 0010]. The reference teaches administration of antigenic fragments to an animal and purifying said induced antibodies [paragraphs 0283 and 0383]. One of ordinary skill in the art would predict that injecting a polypeptide of 111 amino acids (SEQ ID NO:5141) or an antigenic fragment thereof would result in generation of a mix of antibodies, some of which would specifically bind to antigenic epitopes of two or more amino acid residues, including amino acid residues 90-95 of SEQ ID NO:5141; these residues are at the carboxy-terminal end, and would be recognized by the immune system of the animal. These residues are 100% identically to residues 11-16 of SEQ ID NO:1, thereby satisfying the limitation of the claims that the isolated antibody specifically bind to "an amino acid sequence of SEQ ID NO:1 or an immunogenic fragment". One would predict that an antibody which binds to amino acid residues 90-95 of SEQ ID NO:5141 would specifically bind to SEQ ID NO:1, which is an amino acid sequence of 27 amino acids. One would also predict that some of the antibodies generated would specifically bind to

a portion of residues 13-27 of SEQ ID NO:1 since amino acid residues 13-27 of SEQ ID NO:1 of the instant invention comprises a 4-mer that is identical to amino acid residues 90-95 of SEQ ID NO:5141.

Thus, the teachings of the '271 document anticipates all the limitations of claims 1-16 and 52, and the rejection is maintained.

### **New Rejection Under 35 U.S.C. 102(e), Necessitated by Amendment**

Claims 29-38 are newly rejected under 35 U.S.C. 102(e) as being anticipated by Rosen et al. (USPGPUB 2007/0015271, the '271 document.

It is noted that Claim 29, one of the independent claims of the instant invention has been amended. Applicant has deleted the limitation of "having ER- $\alpha$ 36 activity". The Examiner had interpreted this phrase as requiring a unique activity distinguishing polypeptide over the polypeptide disclosed in the prior art. The claim has been extensively amended to now recite "the polypeptide ....is recognized by an antibody that specifically binds to a polypeptide comprising the amino acid sequence depicted in SEQ ID NO:1....." Given the broadest reasonable interpretation, the polypeptide now reads on a polypeptide which would be recognized by the antibody taught by the '271 document.

As stated above, the '271 document teaches a 111 amino acid peptide comprising a 6 amino acid fragment (amino acid residues 90-95) that is 100% identical to amino acids 11-16 of SEQ ID NO:1. The reference teaches antibodies to said polypeptide. One would predict that an antibody which binds to amino acid residues 90-95 of SEQ ID NO:5141 would specifically bind to SEQ ID NO:1, which is an amino acid sequence of 27 amino acids. Thus, the antibody of the prior art would recognize the polypeptide recited in claim 29 ("a polypeptide comprising the amino acid sequence depicted in SEQ ID NO:1"). In addition to the teachings recited above, the reference also teaches that the antibody may be used to detect its cognate protein both *in vitro* and *in vivo* diagnostic methods [paragraph 0345], thus anticipating the limitations of Claims 29, 30 and 33. The antibodies may be conjugated to molecules useful as labels

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in detections assays [paragraph 0346]. The detectable substances may be fluorescent materials [paragraph 0388]. Thus the limitations of claims 37 and 38 are anticipated. The antibody may be used to diagnose (detect) the polypeptide in tissue such as breast cancer tissue [paragraph 0123], thereby anticipating the limitations of Claims 31, 32, 34 and 35. Therefore, the teachings of the '271 document anticipate all the limitations of claims 29-38.

***Conclusion:***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHULAMITH H. SHAFER whose telephone number is (571)272-3332. The examiner can normally be reached on Monday through Friday, 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao, Ph.D. can be reached on 571-272-0939. The fax phone



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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. H. S./

Examiner, Art Unit 1647

/Manjunath N. Rao, /

Supervisory Patent Examiner, Art Unit 1647